



SUMMARY OF SAFETY AND EFFECTIVENESS

- ° This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- ° Identification of Submitter

Larry A. Kroger, Ph.D., 262.544.3894, September 11, 2000

- ° Identification of the Product

Fiesta Imaging Option

Manufactured by:

GE Medical Systems
3200 N. Grandview Blvd.
Waukesha, WI 53188

- ° Device Description

Fiesta Imaging Option is a technique using balanced gradients to maintain phase coherence of the transverse magnetization at each radio frequency (RF) excitation compared to incoherent phase of other techniques.

- ° Indications for Use

The FIESTA Imaging Option is intended for whole body use and is capable of producing high signal to noise images with enhanced contrast and temporal resolution. FIESTA2D and FIESTA3D can be used in clinical applications that benefit from the differentiation of contrast between tissues of low T2/T1 ratios (low signal intensity) and high T2/T1 ratios (high signal intensity). This type of acquisition sequence can be useful for, but not limited to, imaging structures in motion such as the heart with FIESTA 2D or abdominal imaging of the bile ducts using the FIESTA 3D technique. It is also useful for rapid acquisition of static structures with high spatial resolution such as the cochlea or joint imaging

- ° Comparison with Predicate

It is the opinion of GE medical Systems that the FIESTA Imaging Option is substantially equivalent to the Fast Gradient Echo image acquisition sequence in the Signa CV/i MRI System (K980114). Waveform changes enhance contrast and temporal resolution by maintaining phase coherence and shortening the echo and repetition time. This in turn will decrease artifacts associated with motion and blood flow.

- ° Summary of Studies

The FIESTA Imaging Option was evaluated to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. Evaluation testing was done to verify the performance of the option as well as to verify SAR standards of the Signa CV/i are maintained. Patient studies were also performed under IRB to verify that the FIESTA technique presented no significant risk to patients.

- ° Conclusions

It is the opinion of GE that the FIESTA Imaging Option does not result in any new potential hazards.



APR 11 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Larry A. Kroger Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
PO Box 414, W-709
MILWAUKEE WI 53201Re: K002997
FIESTA Imaging Option for MRI
Dated: January 18, 2001
Received: January 19, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002997

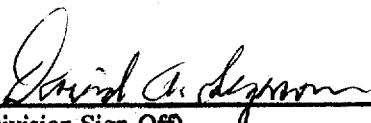
Device Name: Fiesta Imaging Option

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002997

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____